

Carotid Revascularization:

Present Patterns of Use, What Will the Future Hold?

Webcast transcript, August 19, 2010

John Rumsfeld, M.D., Ph.D., Moderator

Slide 1:

DR. RUMSFELD: Good afternoon. This is Dr. John Rumsfeld. I am the Acting Director of Cardiology for the Veterans Health Administration and Professor of Medicine at the University of Colorado Denver. It's my pleasure today to welcome you to our Webcast sponsored by the Agency for Healthcare Research and Quality Effective Health Care Program, entitled Carotid Revascularization: Present Patterns of Use, What Will the Future Hold?

Slide 2:

Our agenda for today's Webcast will be a brief but interactive presentation about a recent study on carotid revascularization, a panel discussion of experts, a question and answer session, a listener feedback poll, and then we will conclude the Webcast. I'll remind all participants that you can e-mail us your questions at any time by entering your question below and submitting it.

Slide 3:

The presentation and panel discussion that we're going to have today do not represent official policy of either the AHRQ or the U.S. Department of Health and Human Services. The views expressed are those of the panelists, and no official endorsement by AHRQ or the U.S. Department of Health and Human Services is intended or should be inferred.

Slide 4:

I'm thrilled today to introduce our panelists. We have an absolutely expert and excellent panel joining us today. Dr. Lesley Curtis is the Associate Professor of Medicine at Duke University School of Medicine, and the Director of the Duke AHRQ DEcIDE Center. Dr. Manesh Patel is the Director of Research of the Cardiac Catheterization Laboratory at Duke University and an interventional and peripheral interventional cardiologist. And, Dr. Ken Rosenfield is the Head of the Section of Vascular Medicine and Intervention at the Division of Cardiology at Massachusetts General Hospital.

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A brief word about the study that we're using to frame our discussion today. First, it was funded by the AHRQ's DEcIDE Network or Developing Evidence to Inform Decisions about Effectiveness. It was conducted at the DEcIDE Center at Duke University. The article was published in the July 26th issue of *Archives of Internal Medicine*, and you can learn more about the study and about the DEcIDE Center at www.effectivehealthcare.ahrq.gov.

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With that, it's my pleasure to introduce Dr. Lesley Curtis to go through the paper. I do want to say that we're going to do this in an interactive fashion, and in each section that Dr. Curtis presents, we're going to have a question or two to start to frame the implications of the results. Lesley.

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DR. CURTIS: Thank you, John. Let me begin by providing a little context for our study. For nearly two decades, carotid endarterectomy has been the recommended treatment for patients with extracranial carotid artery disease. More recently, carotid artery stenting has been proposed as a therapeutic option for patients at high risk for surgical revascularization. There have been several randomized trials comparing endarterectomy with carotid stenting but the results have been mixed.

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In October of 2004, the Centers for Medicare and Medicaid Services issued a national coverage decision supporting the use of carotid stenting for high-risk patients. In light of that decision, we examined the rates of carotid endarterectomy and carotid stenting among Medicare beneficiaries nationwide immediately before and after the change in the coverage.

DR. RUMSFELD: Let me interject there. Manesh, I think it's always good when we've done the background or the introduction of a paper, maybe to reinforce why the study was important to do. What about the clinical practice of carotid stenting at this point in time made this such an important study to undertake?

DR. PATEL: Thanks, John. I guess one thing we wanted to do was to understand, if we go back to 2004, which may seem like a ways away, but in 2004 when the Medicare coverage decision came out, the practice of vascular medicine at that time was patients with symptomatic carotid stenosis or asymptomatic carotid stenosis were considered for revascularization. And Ken and others will speak to this later. As stenting data came and emerged, it was brought to Medicare for coverage and the coverage decision specifically was made that for symptomatic patients that were high risk for surgery, they would be covered for the stenting procedure, and for

asymptomatic patients they needed to be in registry. This was the first time Medicare was making a payment decision on a national level, and what we were trying to do in this study was to understand after this decision was made what were the sort of uptake of the procedure, where was it done, what types of patients was the procedure done in, sort of understanding the landscape after a coverage decision recognizing that that decision was based on the available evidence at that time. And we fully anticipated that these were going to be high-risk patients for surgery because by definition they should be by the coverage decision. But we wanted to know sort of how that affected the care around the country.

DR. RUMSFELD: Thanks, Manesh. Lesley, back to you.

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DR. CURTIS: So we undertook a retrospective analysis of Medicare claims and specifically we analyzed all claims for Medicare beneficiaries who underwent endarterectomy or carotid stenting between January 1, 2003 and December 31, 2006. We used HCPCS/CPT codes to identify the use of carotid endarterectomy and stenting. We also looked for the use of carotid imaging studies in the one year prior to the revascularization date. For this imaging, studies of interest included carotid ultrasound, X-ray angiography and magnetic resonance angiography. Now as the slide notes, we calculated annual age-adjusted rates of endarterectomy and stenting by hospital referral region. You can think of that as sort of a community level and examined the use of carotid imaging prior to revascularization. We also summarized all-cause mortality at 30 days and one year.

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First we looked at how the use of carotid revascularization changed before and after the change in coverage. Now, as shown by the green line on the slide, the rate of revascularization was steady at about 3 per 1,000 beneficiaries during this time period. The use of carotid endarterectomy reflected in the yellow line declined slightly beginning in 2004, and the use of carotid stenting shown by the hot pink line increased slightly beginning in 2004.

DR. RUMSFELD: You know, this is really fascinating, and I want to take a break here and ask Ken to comment. I think that in general when new technology is introduced, when a new percutaneous approach comes on the market so to speak, often we see sky rocketing rates of use of new technology. One might imagine the carotid stenting would take off. The overall rates of carotid endarterectomy might have risen substantially, but we're seeing flat rates of carotid revascularization.

DR. ROSENFELD: That's one of the more interesting aspects of this entire study and what Lesley pointed out of the overall slight decline in global revascularization was I think a surprise to everybody. You're right, one would have expected an explosion. "Oh, now we have something that's less invasive that's available. Patients are going to be knocking down the doors for it." And, as it turns out, I think this is probably due to many, many factors. First of all, as alluded to by Dr. Patel earlier, the Medicare approval was actually quite limited to take the total body of patients that qualify for carotid revascularization, only a small percentage of them are the high-risk individuals that were approved by the FDA for carotid stenting.

Now, within that group of high-risk individuals, a small percentage of those is actually symptomatic and, therefore, CMS from the FDA approval. That is, FDA approved the technology for high-risk individuals, high risk for carotid endarterectomy, whereas CMS limited their payment to those patients who are symptomatic only. Now, that's not to say the asymptomatic patients couldn't participate, but they would have to do so under the aegis of a post market surveillance study, so already the number of people this is really available to is somewhat limited. But I think there are other factors, and I don't want to spend too long on this, but just to say that the other factors that can weigh into the adoption of a technology such as this is the overall enthusiasm for carotid revascularization versus medical therapy; there is new enthusiasm for medical therapy for treatment of carotid disease and the thought that that may actually play a big role in reduction of stroke risk. Lots of other factors, e.g., who is doing the procedures and whether it's really available for all patients is a question. But I think those are the main issues that may have limited adoption and actually caused a decline overall in the carotid revascularization.

DR. RUMSFELD: Really interesting stuff. Lesley, back to you.

Slide 11:

DR. CURTIS: Next we examined how the use of carotid revascularization changed within these hospital referral regions or communities. In 2005-2006, a combined period there, there was a 7- to 9-fold difference between communities with the highest and lowest rates of carotid endarterectomy. So in Beaumont, Texas, for example, the rate of carotid endarterectomy was 7 per 1,000 compared to a rate of 1 per 1,000 in Honolulu. During that same time period, the use of carotid stenting varied at the community level as well. The highest rate was in St. Joseph, Missouri at 2.7 per 1,000 compared to the national average of less than 1 per 2,000.

Interestingly, there was no clear relationship between rates of endarterectomy and stenting at this community or hospital referral region level. In some communities, rates of endarterectomy and stenting were both high while in other communities the use of endarterectomy decreased as the use of stenting increased.

DR. RUMSFELD: So we're seeing here significant geographic variations in both methods of carotid revascularization, both carotid endarterectomy and carotid stenting. In the current health care environment we hear a lot about variation and it's equated to variation in quality of care, and yet here you're talking about at least one of the two therapies is a new or emerging therapy in carotid stenting. You know, it's harder then to know what to make of geographic variations. They are large. They are interesting. What more can we take out of this data? Ken, do you want to comment on that?

DR. ROSENFELD: First, I would say that what struck me was such variation in carotid endarterectomy which is an established therapy. Then you introduce a new therapy and no surprise that you're going to get tremendous variations by geography. There are a lot of moving parts. In some instances you can see some communities where the uptake of all carotid revascularization is quite high. Some of that may be due to health patterns and health of the community. Some of it may be due to physician preferences, and some may be to patient preferences. In other communities you see a switch from one technology to the other and then in others you see that there is little uptake in general. I happen to come from New England and there is a low uptake of both in New England; we're pretty conservative here. I think there is a lot to this that needs to be explored. I think this study is incredibly important because it brings to the fore a lot of questions that need further exploration.

DR. PATEL: I was going to say you hit on all the points as John mentioned. What we have done is made an observation that there is variation and the potential causes are numerous. One thing we know in this study and one thing we know at the same time that we see these revascularization rates being somewhat steady is that the rates of imaging for carotid has certainly gone up, and at least an interesting finding from this study was that up to a quarter of the study that had carotid revascularization or carotid endarterectomy had an ultrasound before going to the procedure and there was variation in how many patients got ultrasound and other non-invasive imaging modalities. So another driver for revascularization may be the threshold to image the carotids and then how many studies occur in these patients.

DR. RUMSFELD: Ken and Manesh, thank you for your comments. And Lesley, that's a perfect bridge to our next slide about carotid imaging.

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DR. CURTIS: So as Manesh noted, among those patients who underwent carotid endarterectomy, 27 percent received only a carotid ultrasound in the 365 days prior to revascularization. Now, the majority of patients in both the endarterectomy and the stenting cohorts received an ultrasound and either an MRA or X-ray angiography prior to the

revascularization. And, one in five patients who underwent carotid stenting received ultrasound, MRA, and X-ray angiography in the year prior to revascularization.

DR. RUMSFELD: You know, I can't decide myself if the variation in carotid revascularization or the variation in imaging prior to revascularization are more important or more interesting. Manesh, let me ask you, you alluded to it a little bit, but are there any specific guidelines or appropriate use criteria, anything that guides which of these modalities need to be done? Or is it so patient-specific in terms of anatomy that it's totally reasonable you may do one, two or all three? Is there anything we can read into this?

DR. PATEL: I think it's hard to fully interpret. I will say that there are some general guidelines from the ACC and AHA on how to evaluate carotid disease, but which imaging studies, how many of them to do and the common clinical questions on how often to repeat image patients with intermediate to moderate disease have not been addressed previously.

There is a movement within the American College of Cardiology to have carotid appropriate use criteria coming forth in the next year or so, I believe.

I guess one sort of interpretation, at least from the revascularization interventional or surgical perspective is your comfort level with the imaging before you do the procedure. Ken, can you speak to this, too, maybe. Some places, if there is a good ultrasound lab and the surgeons feel comfortable with the findings, they'll go directly to surgery. Other places, they want a CT or MR or X-ray angiography. If you are going to be doing stenting, you're going to be doing angio. It may deal a little bit with what the national standards on how well the images are taken. I don't know what your feelings are about going to a revascularization with one study or more.

DR. ROSENFELD: First of all, those patients undergoing carotid stenting will generally have an angiogram done prior to stenting. So I'm not sure to what degree those data were included in this, but I would say that over the past ten to fifteen years since carotid stenting has come to the fore, I've seen a great evolution in the approach to carotid artery disease. I mentioned earlier the neurologists and others of us excited about medical therapy production with statins and the same therapies that have reduced cardiovascular disease, but in addition early in the 90's there were some studies that were published in the surgical literature suggesting that ultrasound is the gold standard and that's all you need in order to justify going ahead with revascularization.

I do think that ultrasound performed in a certified high-end laboratory is a superb study and can be adequate as a single test, in many instances. In many of patients that we are talking about who underwent carotid stenting, remember I said that these are completely different patients; they are the high-risk patients. They are not the standard, average, ordinary patient who goes through endarterectomy. And because they are higher risk, many of them may have been subjected to

additional testing, CTA, and MRA, noninvasively, prior to deciding to move forward with revascularization. So I think that may also play a role in the differential imaging.

And finally, I think there has been an evolution in the management of this disease such that people want more information before they decide to go forward with revascularization. In our institution, there is really a requirement for two studies. You need an ultrasound and you need some kind of axial imaging study or angiograph before deciding to revascularize, and I think that has become the standard for many of us and many in the neurology community before recommending revascularization by either method.

DR. PATEL: This is Manesh, and I agree with you. I think the neurology input has increased our want to evaluate other vascular beds as the cause of TIA or stroke and take it beyond the carotid imaging.

DR. ROSENFELD: You mean more distal beds.

DR. PATEL: And MCA disease, et cetera.

DR. RUMSFELD: So great comments. And Lesley, let's look at the outcomes.

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DR. CURTIS: We tabulated all-cause mortality rates in each cohort. I show 30-day here and the 30-day mortality rate for endarterectomy was 1.2 percent and the 30-day mortality rate for stenting was 2.3 percent. Now, both are higher than those reported in the clinical trials, but that difference is to be expected given the elderly population included in this analysis.

DR. RUMSFELD: And for those that have read the paper, of course the one year mortality rates sort of mirrored this. Again, much lower mortality in the CEA patients than in the carotid stenting patients. Now I think one of the take-home messages that I'd like to propose for this Webcast today is that it would be wrong to look at the results of the study as a comparative effectiveness study of carotid endarterectomy versus carotid stenting. I think it's very important because while there are differences here in outcomes, I think it's directly related to differences in the patients. Ken, can you comment on that?

DR. ROSENFELD: You've stated it nicely, John. These are apples and oranges. The patients who underwent endarterectomy are lower risk by definition. And, you know, the patients by definition that went through carotid stenting are high-risk patients because the therapy was not approved for the low-risk individuals. So what you saw was, if anything, based on Lesley's earlier slide a shift in some from endarterectomy to stenting. And now the patients are undergoing stenting and, no surprise, you're going to see a higher mortality. I think that it's

important to look at the recent CREST study which was recently reported that showed for conventional risk patients, carotid endarterectomy and carotid stenting actually have the same outcome, both in one year and beyond. So if you're really going to do a comparative effectiveness and compare the outcomes of these two therapies, the best way is prospective randomized trials like the CREST trial.

So the trial that compared these two groups of patients head to head for the high-risk group, the Sapphire Trial actually showed that if you take apples and apples, they come out just about the same with these two therapies.

DR. RUMSFELD: I think that you're making a great point, and we're going to talk a little more about CREST and the comparative effectiveness in the questions that are being submitted to us. By the way, the differences in mortality are a reflection of patient characteristics is clear if you look at the table or baseline characteristics of the patients in the paper.

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So, Lesley, we're going to move to the question and answer session now. We can go to the next slide. And as we head into this, Lesley, let me ask you if you could just summarize for us what you consider to be just sort of the take-home message for someone who has read this paper.

DR. CURTIS: I guess I'd offer the following: First, the use of carotid revascularization has remained quite steady in this period surrounding Medicare's national coverage decision, but there remains considerable geographic variation as we've discussed in the use of these procedures.

Maybe the other smaller take-home message is that the use of imaging studies prior to revascularization varies quite a bit as well and we're not quite sure why.

DR. RUMSFELD: Thanks, Lesley. And, Ken, so a question for you. The results of the CREST study that you mentioned were published May of 2010. Is CREST -- what does CREST add? Is it a game-changer? Is this going to change the future of carotid stenting?

DR. ROSENFELD: I think it should and it will. You know, an NIH-sponsored and funded multi-center trial with 117 sites with all kinds of different operators from all different kinds of specialties showing that carotid stenting is equivalent to endarterectomy for the conventional risk patients both symptomatic and asymptomatic has to be considered in coverage and should -- and you know that is an alternative for patients who are looking for revascularization and need revascularization. It should be there. We have no idea what Medicare will do and of course this has to go through its usual processes, the FDA has to approve the therapy and then Medicare has to consider payment issues. We don't know how they will respond, but certainly it should be a game-changer.

DR. RUMSFELD: Manesh, let me ask you what I know is not an easy question, but one that we'd really like to spend a little time on here.

You've already alluded to, Ken's alluded to and AHRQ would like to know this, what is next for research? In other words, what research still needs to be done at this point? And I really think we should break it into two sections, what additional research could be done through networks like DEcIDE which tend to have more observational but often very rich clinical, longitudinal data and/or use of Medicare claims. What more could we do through, say, a DEcIDE research? And the second part is, which clinical trials need to be done in your view?

DR. PATEL: Thanks. I'm sure Ken is leading one of the larger trials right now and he can speak to it, too, but I think there is sort of a few areas that in clinical practice we still will be struggling with that I think will be answered hopefully in the next few years. First is what we've shown with the Medicare decision with some DEcIDE type and some observational analysis that there was a change in practice, but I think Medicare wanted to control the roll-out of carotid stenting and make sure there wasn't an explosion and the high-risk patients got the stent that would not have been potentially the ideal surgical candidates and that's what the observation likely showed.

What we now need with the randomized trial data that has come out from observational analysis is to continue to see how the practice is changing. What are the patients looking like as we get towards continued care both stenting and surgery and continue to improve. Are the outcomes improving? Are the patient demographics changing? And is the decision moving towards lower risk patients for stenting and revascularization?

Another very important question that has not been answered by either modality is patient preference and the drivers for patients and how do we frame this decision and discussion for patients regarding their decision to undergo carotid revascularization. And within that discussion obviously is an important arm that a lot of our neurological colleagues will speak to is that the medical therapy arm has improved significantly over time and the next set of carotid revascularization studies likely will at least attempt to and hope to have some medical therapy arm, It's what's being asked for from our neurologic colleagues. I would say that a large trial in patients with asymptomatic stenosis evaluating stenting within a randomized format, the Act I trial, has been led by Ken who is on this call and others. I think that will be an important study to help us understand the lower risk patients and how they are revascularized. I would make it three groups, what are patient preferences and what are the drivers. I think we have to spend a lot of time with that because in the clinic room, just having this discussion takes awhile and understanding patient preferences is important and figuring out better ways to have that discussion and drivers would be important. Two, observations to preserve and to understand that as we continue to apply our randomized data that the patient population getting these therapies

seems to be where we think there is most benefit. And three, ongoing clinical trials to both understand medical therapy and the asymptomatic population.

DR. RUMSFELD: Well stated. And Ken, would you add anything to that?

DR. ROSENFELD: What Manesh is referring to, the trial that I'm involved with, my colleague, who is a surgeon, Dr. John Matsumura, is the Act I trial which is a prospective randomized trial comparing endarterectomy to stenting for conventional risk asymptomatic patients whereas CREST involved both symptomatic and asymptomatic patients. This trial was powered to look only at the asymptomatic patients, which makes up the largest group of patients that undergo revascularization in this country right now. That trial is well underway, two-thirds enrolled, with 1,700 patients, and I think that will be informative. I agree with Manesh that the role of medical therapy having evolved over time does bring to the fore the question about what's the threshold for revascularization. We can see that with a gradual decline in overall rates of everything. So I think that the next step will be to compare medical therapy in the current era to optimal medical therapy to best carotid revascularization for that given patient. And that will be something that will happen I think over the next five years, where we'll see a trial develop in that regard.

One of the difficulties here is it's very expensive to run these trials, and that's where the DEcIDE Network and other formats for getting at this information will be important. John, you to some degree are involved and I'm involved with the so-called CARE registry which is run by the NCDR and my hope would be that the CARE registry which accumulates prospectively much more information than can be acquired by an administrative database. So, for example, what are the individual risk factors for a given patient who needs revascularization and how do those individual risk factors direct somebody towards one therapy over another? What makes them high risk for one thing or another? My hope would be the combination of the DEcIDE Network's working with the registry formats might actually enlighten practitioners, as you say.

DR. RUMSFELD: So Ken, you have a lot of interest in what the role of clinical registry is here. You've mentioned the CARE registry. You're one of the leaders of the CARE registry. Ken, it would be useful to give a quick overview of what's in the CARE registry. I know you feel passionately about one of the 30-day neurological outcomes in it.

What can we use for the CARE registry to inform observations about effectiveness potentially, and/or patient safety and/or important outcomes and/or device surveillance? What should we be doing with the clinical registries and maybe I'll ask Manesh how we bring that together with, say, a DEcIDE Network. Manesh and Lesley, we bring that together with DEcIDE. Tell us a little more about CARE.

DR. ROSENFELD: CARE is a carotid artery revascularization registry. It's run by the NCDR. John, you do have a conflict here. You're the chief scientific officer and I'm one of the leaders and developers of the CARE registry. The bottom line is that it has sites around the country that will submit all of their data on carotid revascularization on both stents and endarterectomies performed in their individual hospital sites. And the data are robust, there are some 200 elements that we ask to be completed and it's much akin to a clinical trial in that we gather all of the risk factors associated with a given patient who undergoes revascularization. And that is, then entered into a large registry and individual sites can benchmark their results against the results nationally, but in addition to that, we hope that with enough data looking at the characteristics of the patients and the outcomes, we can do risk adjustment models so that we can determine a given patient coming to your office with congestive heart failure and this cholesterol profile and that age and these anatomical characteristics, will have such and such a risk for one therapy versus another. And maybe they shouldn't have either. So, I think these are going to be very powerful ways to help patients in the future.

The one thing that I will mention that you highlighted is the 30-day outcome issues. One thing that CARE does include, which is one of the first registries to do so, is a 30-day stroke and death and MI outcome. And importantly, in order to look at these outcomes appropriately, you need to really have independent analysis or independent adjudication of the outcome of stroke. It's so important in order to be able to compare apples and apples, you need to be able to have the same outcomes looked at by the same mechanism which is an independent, neurologic adjudication. Any study you look at with carotid revascularization, you must first ask the question, are the outcomes the same using the same parameters? Is there an independent or objective assessment of neurologic status at 30 days?

DR. RUMSFELD: I think that's a great point. Manesh, do you want to add anything on this point?

DR. PATEL: Ken, you obviously lead the field in how we think of clinical data and clinical registries, and I would say this is an exciting time not just for carotids, but all of vascular medicine because what we're getting to now is that there is a point where we can participate hopefully without great effort in our clinical practice so that our patient care information gets put into a larger data pool so that we can do one of two things. We can compare our own practice, but we can start to understand more of the clinical depth of the patients going through these procedures or different types of care. We can do things like device surveillance, but I think what happens is we may have the opportunity now to link that to longer term outcomes with some of the linkage to Medicare data that's ongoing with our group and other groups. And the other thing is I think we end up informing ourselves, a simple example with the drug-eluting stent story and antiplatelet therapy, we realize that's an important marker for outcome of patients and we

incorporate it into our registries and we're following them long-term to see how they do. One could argue no matter how you get carotid revascularization, that would be another but not as well answered question yet, how much and how long is antiplatelet therapy continuing in these patients. We may inform other things we haven't thought about, medical procedures around the procedure, the sorts of device or other complications. A lot of the surgical literature is about the types of patches being used versus other things for carotid revascularization. So I think we improve our care and we also inform ourselves as we go forward, and I think it's an exciting time for people to ask those questions and hopefully continue to do it.

DR. RUMSFELD: Let me ask Lesley one of the questions that's been posed is that this analysis that we're centering our conversation around today was done with data that are now somewhat dated or old. So what do you think if we repeat the study with current data, do you anticipate it would look any different but not that much has changed in the field? And/or would that be informative or do we really need to move on and think about other comparative effectiveness studies where we account for, for example, medical therapy?

DR. CURTIS: It's a great question about whether or not the data that we present here would in fact reflect practice today. And I'm not sure that we know the answer to that, but I would probably guess that they are more or less accurate. For example, in the geographic variations, we've seen that in carotid endarterectomy certainly for 10 or 15 years now. So I would doubt anything there has changed over the last few years.

A point that Manesh made kind of resonates here as well and I think that there is opportunity to do more work with these kind of data to show how the different therapies are being used in this population. But I think we can move beyond the kind of data that are shown just in this paper. So I really do believe that we can move beyond this. We don't need to replicate this specific analysis.

Manesh and Ken have articulated nicely the real potential and value of observational data to address key questions in this area. And, all of us I think would agree very strongly that observational data are not the data to be used really for those comparative effectiveness studies.

So that's going to be the challenge going forward.

DR. ROSENFELD: One of the other things that would be interesting, Lesley, and comment on this, if you would, as Manesh pointed out, there are going to be guideline criteria for the treatment of extracranial carotid disease that are going to be published over the next six months from the AHA, ACC and others. And I think it would be fascinating to look at the before and after of that, that is, a biopsy of what's happening now versus two years from now after the new guidelines are published.

DR. CURTIS: Absolutely. I think that's a great example. The caveat, is that in these claims data we're really restricted in terms of the kind of clinical information we have. So information data points that are required for reimbursement tend to be very well coded. Those that are not, tend to be less well coded. So with the caveat that we have limited clinical data in these data sets, I couldn't agree more with your suggestion.

DR. RUMSFELD: All right. We do have one more question posed here, which this is easy, Ken, no problem. Do you consider at this point in time, but also trying to look ahead, which I know is a tough one, are carotid endarterectomy and carotid artery stenting competing or complementary procedures, and is this going to change over time?

DR. ROSENFELD: I think they are complementary. No doubt. You know, my own vision is that -- and I have done this a lot and been involved in the field for extensive periods of time, at the end of the day there will be patients who are appropriately vascularized and those who will not be, and I think that requires an upfront decision. Once you decide the patient is appropriate to revascularize for stroke prevention, and we have to keep in mind that's the reason we're revascularizing, then there will be some portion of patients, let's just guess that it's going to be 20 or 25 percent of patients who are clearly going to be better for endarterectomy. There is going to be 20 or 25 percent of the patients who are clearly going to be better for stenting and then there is going to be the patients in the middle, 50 percent of patients or so who could have either therapy and there will be many factors that will help one decide: patient preference, physician preference, physician experience, availability of the techniques and personnel who can do them, and other clinical risk factors that will hopefully be better defined by the CARE registry and some of the DEcIDE Network research and other research going forward. So I think these are complementary, absolutely, and the thing is to do the best thing for that individual patient, factoring in all the data that are available at one's behest.

DR. RUMSFELD: Well stated. Manesh, you want to have one last word.

DR. PATEL: I totally agree. I think they are complementary, and as we evolve in the next five to ten years as more of our surgical colleagues do both endovascular and surgical revascularization that the ability to identify patients will become less contentious and become easier because I think patients and clinicians will understand some of the breaking points for which method.

DR. RUMSFELD: Great point. Okay, well, thank you. Excellent and great discussion.

Slide 15:

With that, I'd like to thank everyone for your participation. Thank you very much to the panelists, excellent conversation, and thank you very much for all the participants. Please join

the e-mail list to receive news about the EHC Program as indicated on the slide, and with that I'll thank you and wish you all a good day.

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